

REMARKS

I. STATUS OF CLAIMS AND FORMAL MATTERS

Claims 28-31 and 34 are under examination in this application. Claims 28-30 and 34 have been amended; claims 1-27, 32 and 33 have been cancelled without prejudice.

Support for the claim amendments can be found throughout the specification. In particular, support for “position 1 to position 341” of SEQ ID NO:6, as recited in claims 28 and 34, and for “position 342 to position 1041” of SEQ ID NO:6, as recited in claim 34, can be found on page 17, lines 5-7, of the specification. Support for “position 1 to position 342” of SEQ ID NO:10, as recited in claim 34, and for “position 343 to position 484” of SEQ ID NO:10, as recited in claims 28 and 34, can be found in the sentence bridging pages 17 and 18. Support for “a sequence within SEQ ID NO:1 from position 412 to position 1746”, in claim 28, can be found in the table on page 16 of the specification, entitled “Table: genetic elements of vector pUC/Ac”. The table explains the different elements that make up SEQ ID NO:1. As can be seen from the table, and from the attached diagram, positions 412 to 1746 are the promoter, coding region and terminator of SEQ ID NO:1, while positions 1747-411 of the plasmid sequence include vector backbone sequences, the β -lactamase gene and the origin of replication. Support for the hybridization conditions recited in claims 28, 30 and 34 can be found in the section of the specification beginning on page 20, line 17.

No new matter is added by this amendment.

It is submitted that the claims, herewith and as originally presented, are patentably distinct over the documents cited by the Examiner, and that these claims were in full compliance with the requirements of 35 U.S.C. §112. The amendments of and additions to the claims, as presented herein, are not made for purposes of patentability within the meaning of 35 U.S.C. §§§§ 101, 102, 103 or 112. Rather, these amendments and additions are made simply for clarification and to round out the scope of protection to which Applicants are entitled.

II. THE REJECTION UNDER 35 U.S.C. §112, 1ST PARAGRAPH, IS OVERCOME

Claims 28-34 were rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking adequate written description. The rejection is traversed.

Initially, it would appear as though further explanation of elite events in general, and elite event GAT-ZM1 specifically, would be useful. The Office Action states on page 3 that “the term

GAT-ZM1 is not limited to a single event in a single strain of corn". This statement is misguided. By its very definition, an elite event is the incorporation of a transgene or "foreign DNA" into one specific locus in the host genome. A plant is transformed, bred and/or back-crossed so that it contains the foreign DNA at a locus that satisfies several criteria, as outlined beginning on page 7, line 8, of the specification.

The attached diagram schematically represents the insertion of the phosphinoacetyltransferase ("pat") gene for elite event GAT-ZM1 in the chromosome of corn, and indicates the interrelationship between the amplified flanking fragments and primers described in the Examples and their nucleotide sequences as set forth in the sequence listing. SEQ ID NO:1 is the entire vector comprising the transgene to be introduced into the corn plant. The transgene itself spans positions 412-1746 of SEQ ID NO:1, and is represented by the heavy black arrow. The vector is transformed into plants, and the transgene incorporates at a different locus in each plant. In the attached diagram, the transgene, or foreign DNA is shown in red and the native plant DNA is shown in green. The plants are evaluated based on the criteria described on page 7 of the application, and a plant with desirable traits is chosen. This plant comprises the elite event, in this case, elite event GAT-ZM1. It is important to note that every plant that is described as comprising elite event GAT-ZM1 has the transgene encoding phosphinoacetyltransferase integrated into its genome at the same locus. If this were not the case, the sequences of SEQ ID NO:6 and SEQ ID NO:10 (referring again to the attached diagram) would be different for every plant because the sequence of the green portion would change, depending on where in the genome the transgene was integrated in any given plant.

In any event, claims 28 and 34 have been amended, to recite specific nucleotide positions within the flanking regions (SEQ ID NO:6 and SEQ ID NO:10) and the vector (SEQ ID NO:1). The claims have further been amended such that the primers "consist of" 15 to 30 nucleotides from the recited sequences. Thus, the claims are not drawn to a nucleic acid that can be amplified by a primer with a small degree of complementarity to SEQ ID NO:6 or SEQ ID NO:10 and a primer with no defined sequence. Rather, the claims are drawn to a nucleic that can be amplified by a primer having complete sequence identity with the corn-specific sequences flanking the insertion of the pat gene in elite event GAT-ZM1, and a primer identified as having

a length of 15 to 30 nucleotides selected from the specific sequence of the foreign DNA used to generate GAT-ZM1.

Indeed, a person skilled in the art, would immediately realize, upon reading the specification, that the claimed genus of DNA fragments covers any DNA fragment selected from the DNA fragments that, depending on the choice of first and second primers, either have a “starting point” in SEQ ID NO:6 that is between positions 1 and 341 and an “end-point” within SEQ ID NO:1 between positions 412 and 1746; or have a starting point in the nucleotide sequence of SEQ ID 1 between positions 412 and 1746 and an end point within the nucleotide sequence of SEQ ID 10, between positions 343 and 484. Thus, all DNA fragments of the claimed genus are fully characterized by their nucleotide sequence, and all are unique for elite-event GAT-ZM1. The skilled artisan could thus immediately envision the detailed chemical structure of the encompassed polynucleotides. Admittedly, the claims are drawn to a genus of DNA fragments, however, all of these DNA fragments are fully characterized by their nucleotide sequence, and will differ only in length (save for some errors introduced by PCR amplification).

The Office Action also indicates that, due to non-specific amplification of DNA fragments resulting from PCR amplification, the instantly pending claims thus encompass a large genus of non-specifically amplified DNA sequences as well. Claims 28, 30 and 34 have been amended to recite PCR conditions with the particular thermocycling profile used in the Examples of the current application. As can be seen, *e.g.* from Figure 1 of the application, use of these conditions does not result in amplification of non-specific DNA sequences. Therefore, the rejection on this basis is now moot.

It is thus submitted that the assertion in the Office Action that numerous different DNA molecules are encompassed in the scope of the claims is not correct. Though the claims may encompass sequences of different length, they are all obtained by amplification of DNA from a plant comprising GAT-ZM1 of a region spanning the 5' flanking sequence and the foreign DNA contiguous therewith, or the 3' flanking sequence and the foreign DNA contiguous therewith. Though the specific primers may change, resulting in DNA molecules of various lengths, the template is the same, so that these DNA molecules, which are all characteristic for DNA comprising elite event GAT-ZM1, will all be, at least partially, overlapping.

Thus, given the fact that the claims clearly refer to DNA sequences that can be obtained from the DNA of a plant comprising elite event GAT-ZM1, it is submitted that the description clearly conveys to a person skilled in the art that the Applicant was in possession of the invention when the application was filed. Reconsideration and withdrawal of the rejection under §112, first paragraph, are requested.

III. THE REJECTIONS UNDER 35 U.S.C. §102 AND §103 ARE OVERCOME

Claim 28 was rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Accession number A17373. Claim 31 was rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Accession number A17373 in view of Ahern. The rejections are traversed.

In making this rejection, the Office Action argues that A17373 teaches a sequence from SEQ ID NO: 10, which is part of an artificial pat gene and that such a sequence could be amplified by a primer which is complementary to a sequence within SEQ ID NO:10 and a primer complementary to foreign DNA. Applicant agrees that A17373 teaches a sequence of an artificial phosphinotransferase gene, similar to the one currently used to generate corn elite event GAT-ZM1, and that part of this sequence (from nucleotide 86 to nucleotide 427 corresponds to the complement of part of the nucleotide sequence of SEQ ID NO:10, namely the part from nucleotide 1 to nucleotide 342. In fact, this is indicated in the specification, in the sentence spanning pages 17 and 18, where it is said that the nucleotide sequence represented in SEQ ID NO:10 corresponds to nucleotide 1 to nucleotide 342 of the transforming DNA, which, for GAT-ZM1, consists of an artificial phosphinotricin phosphotransferase gene. The Examiner's attention is again referred to the attached diagram. It should be appreciated that it is the primer pair, wherein one primer corresponds to the pat transgene sequence (represented in red in the diagram) and the other primer corresponds to specific plant DNA flanking the insertion site (represented as green in the diagram), that amplifies the particular elite event GAT-ZM1. If the sequence taught in Accession number A17373 is used as a primer, but is not paired with a primer containing a native corn DNA sequence that flanks the particular unique insertion site of elite event GAT-ZM1, the claimed DNA molecules will not be amplified. The nucleotide sequence of Accession number A17373 does not include this GAT-ZM1 specific plant sequence of at least 15 to 30 nucleotides, and thus cannot anticipate the currently claimed DNA fragment.

For the reasons indicated above, the nucleotide sequence of Accession number A17373 does not include a GAT-ZM1 specific plant sequence of at least 15 to 30 nucleotides, nor does it teach or suggest the use of one. This deficiency in the primary reference is not cured by the secondary reference, as Ahern remains completely silent concerning the teaching of DNA fragments with GAT-ZM1 specific corn sequences adjacent to the pat transgene insertion site.

It is clear from the above argumentation that the claims under consideration in the instant application are neither anticipated nor rendered obvious by the references cited in the Office Action. Accordingly, reconsideration and withdrawal of the art rejections are requested.

CONCLUSION

Applicants believe that the application is in condition for allowance, and favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited. If the Examiner would benefit from further clarification, she is invited to contact the undersigned prior to the issuance of any further action.

Respectfully submitted,

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